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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,717	11/08/2001	Jay S. Huebner	UNF-HUEBNER	7693

26033 7590 07/02/2003

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EXAMINER

SNAY, JEFFREY R

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-5

<b>Office Action Summary</b>	<b>Applicati n N .</b> 10/005,717	<b>Applicant(s)</b> HUEBNER ET AL.	
	<b>Examin r</b> Jeffrey R. Snay	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al.

Clarke et al disclose a method for detecting an analyte comprising providing a sensor, which sensor comprises a polymeric film and reagent dye, and contacting a sample with the reagent dye. A colorimetric reaction occurs between the dye and analyte such that the absorbtive properties of the dye are altered. A light source directs light through the polymer and to the reagent dye, such that the increased photo-absorbtion of the dye causes localized heating, resulting in the generation of electrical movement in the sensor device. The generated electrical energy is monitored and related to the concentration of analyte in the sample. See Clarke et al at columns 4 and 5. Regarding instant claim 7, see Clarke et al at column 5, line 4 disclosing the illumination of the dye at a preselected wavelength. Regarding instant claim 9, see Clarke et al at column 5, lines 49-65, disclosing an embodiment in which a plurality of different reagent dyes are provided on the substrate in order to enable detection of multiple analytes.

Art Unit: 1743

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4-6 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al.

Regarding the presently claimed method, Clarke et al differs in that it fails to disclose the measurement of unreacted dye (claims 4 and 10), and the selection of a particular duration of illumination. However, the measurement of a signal in an analytical sensor prior to reaction with a sample was notoriously well known in the art in order to account for background signals generated by the sensor device, optics and electronics. The selection of duration of illumination in the method of Clarke would have constituted optimization of a known result effective variable, conditioned only on the particular dye and sample being investigated. The presently claimed generation and use of a calibration curve are present in Clarke et al as depicted in Figure 2.

Regarding the presently recited apparatus, the apparatus of Clarke et al, depicted in Figure 1 differs from that claimed by applicant only in that Clarke et al fail to disclose the sensor device being positioned within a container to which a sample is to be added. The provision of such a container would have been obvious to one of ordinary skill in the art in order to enable analysis of larger volumes of sample, or alternatively as a means for precluding interfering substances from contacting the sample and the detected surface of the sensor device.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general background information related to applicant's field of endeavor.

Art Unit: 1743

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jeffrey R. Snay  
Primary Examiner  
Art Unit 1743

jrs  
June 28, 2003